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10/586,165	11/19/2007	Mitsuhiro Shikida	450104-05892	5637

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EXAMINER

PREGLER, SHARON

ART UNIT	PAPER NUMBER
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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,165	Applicant(s) SHIKIDA ET AL.	
	Examiner Sharon Pregler	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-28 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/14/06</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claim Objections

1. Claim 17 is objected to because of the following informalities: "arranges" should be "arranged" on line 13, "an" should be "a" on line 14. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 2 of claim 17, "a very small amount of droplet" is unclear. Since the applicant's specification indicates that the channels are micro-sized it is taken that the volume of "a very small amount of droplet" is sufficient to fit within micron-sized channels.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. ***Claims 17-19 & 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein US Patent 6,432,630 (hereinafter "Blankenstein") in view of Ward et al. US Pre-Grant Publication 2004/0018611 (hereinafter "Ward").***
5. **Regarding claim 17, Blankenstein teaches** an chemical analytic apparatus (*microflow system 1, figure 1, column 12 line 62 – column 13 line 12*) which performs various kinds of processing for analyzing a very small amount of droplet chemically (*column 1 lines 20-30*), including:

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6. in a condition where magnetic ultrafine particles (*magnetically stained particles 12 in sample 9, figure 1*) are mixed to a droplet (*column 3 line 65 – column 4 line 10; column 12 lines 50-60, figure 1*),
7. a conveyance means (*flow channel 5, figure 1 column 12 lines 60-65*) by which the droplet to which said magnetic ultrafine particles were mixed is conveyed in another liquid (*buffers 10 & 11; it is well known that buffers may be fluid; enter flow channel, column 13 lines 1-5*), for processing of chemical analysis, by applying magnetic field (*field generating means with a magnet 8, column 13 lines 1-5*) to said magnetic ultrafine particles; and
8. a processing means (*detection means 16, figure 2*) by which operations for processing of chemical analysis are performed one by one in the process in which the droplet to which said magnetic ultrafine particles were mixed is conveyed by said conveyance means (*column 12 line 62 – column 13 line 12, figure 1*), wherein
9. plural kinds of the droplets (*the droplets are considered as intended use and do not add weight to the apparatus claims for patentability*) to which said magnetic ultrafine particles are mixed and of only the droplets are provided, and said processing means includes small compartments (*collection chamber 37, column 16 lines 35-45, figure 7*) separated by plural bulkheads (*protrusion of outlet 6 & 7, figure 1*), and said plural kinds of droplets to which said magnetic ultrafine particles were mixed or only the droplets are arranged in each said small compartment (*collection chamber 37*), and
10. an droplet to which said magnetic ultrafine particles are mixed and which is arranged in an optional small compartment (*the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1*) is conveyed by said conveyance means, by passing through each bulkhead provided in each said small compartment, and a chemical reactive operation itself or part of the operation is performed by uniting it with the other droplet out of said plural kinds arranged in the other small compartments. (*See figure 1, 6-7, column 1 lines 20-30, column 3 line 65 – column 4 line 10, column 12 lines 50-65, column 13 lines 1-15 & 40-50, column 16 lines 35-45*).
11. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein is a protrusion within the channel and effectively sorts fluid as the bulkhead

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described in the specification where it separates the fluid into another compartment (*outlet 6*). Furthermore Ward teaches it would have been obvious to have bulkheads valleys, pits, or protrusions (*See Ward Figure 7 & [0289]-[0290]*) to define chambers for separation for the benefit of separating molecules based on molecular size, shape, and/or charge (*[0134]*).

12. Therefore it would have been obvious to modify the channel of Blankenstein with pits or bulkheads of Ward for the benefit of separating molecules based on molecular size, shape, and/or charge.

13. **Regarding claim 18, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein

14. when an optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed and which is arranged in an optional small compartment is conveyed to said other small compartment (*the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1*) by said conveyance means by passing through each bulkhead provided in each said small compartment (*column 13 lines 1-10*),

15. the optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed is separated (*separation occurs after magnet 8 toward sort outlet 6, figure 1*) to the droplet that includes said magnetic ultrafine particles (*column 13 lines 5-9*) and the droplet that does not include said magnetic ultrafine particles (*column 13 lines 9-12*), by using physical and chemical characteristics such as wettability and surface tension of said droplet (*column 13 lines 13-20*).

16. **Regarding claim 19, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein

17. by controlling the magnetic field which is externally applied to the droplet to which said magnetic ultrafine particles are mixed, said magnetic ultrafine particles are dispersed and cohered in the inside of the droplet, and also the operation of the droplet to which said magnetic ultrafine particles is performed. (*Column 3 line 65 – column 4 line 10 & column 5 line 60-65, column 6 line 20-35, & column 9 lines 10-40*).

18. **Regarding claim 21, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein

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19. in the condition where a specimen for performing chemical reactive operation adhered (*magnetically stained particles, column 3 line 67 column 4 line 9*) to surfaces of said magnetic ultrafine particles, said magnetic ultrafine particles are used as a carrier to perform the chemical reactive operation to said specimen (*column 13 lines 1-15*).
20. **Regarding claim 22, Blankenstein teaches** the chemical analytic apparatus according to claim 17, wherein
21. by combining a plurality of said small compartments (*the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1*) which are separated by plural bulkheads and which become said processing means, a series of chemical reactive operation by at least reaction, separation and dilution to a specimen that adhered to surfaces of said magnetic ultrafine particles is performed. (*See figure 1, & column 1 lines 20-30*).
22. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein is a protrusion within the channel and effectively sorts fluid as the bulkhead described in the specification where it separates the fluid into another compartment (*outlet 6*). Furthermore Ward teaches it would have been obvious to have bulkheads valleys, pits, or protrusions (*See Ward Figure 7 & [0289]-[0290]*) to define chambers for separation for the benefit of separating molecules based on molecular size, shape, and/or charge (*[0134]*).
23. Therefore it would have been obvious to modify the channel of Blankenstein with pits or bulkheads of Ward for the benefit of separating molecules based on molecular size, shape, and/or charge.
24. **Regarding claim 23, Blankenstein teaches** a chemical analytic apparatus (*microflow system 1, figure 1, column 12 line 62 – column 13 line 12*) which performs various kinds of processing for analyzing a very small amount of droplet chemically (*column 1 lines 20-30*), including:
25. in a condition where magnetic ultrafine particles (*magnetically stained particles 12 in sample 9, figure 1*) are mixed to a droplet (*column 3 line 65 – column 4 line 10; column 12 lines 50-60, figure 1*),
26. a conveyance step (*flowing through flow channel 5, figure 1 column 12 lines 60-65*) by which the droplet to which said magnetic ultrafine particles

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- were mixed is conveyed in another liquid (*buffers 10 & 11; it is well known that buffers may be fluid; enter flow channel, column 13 lines 1-5*), for processing of the chemical analysis, by applying magnetic field (*field generating means with a magnet 8, column 13 lines 1-5*) to said magnetic ultrafine particles; and
27. processing steps (*detection means 16, figure 2*) by which operations for processing of chemical analysis are performed one by one in the process in which the droplet to which said magnetic ultrafine particles were mixed is conveyed by said conveyance step (*column 12 line 62 – column 13 line 12, figure 1*), wherein
28. plural kinds of the droplets to which said magnetic ultrafine particles are mixed and of only the droplets are provided, and the processing conditions by said processing steps are formed in small compartments (*collection chamber 37, column 16 lines 35-45, figure 7*) separated by plural bulkheads (*flow through controlled by valves in column 7 lines 35-45*), and said magnetic ultrafine particles of the plural kinds are arranged in each said small compartment (*collection chamber 37*), and
29. an optional droplet out of said plural kinds of droplets (*see below*) to which said magnetic ultrafine particles were mixed and which is arranged in an optional small compartment (*the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1*) is conveyed by said conveyance means by passing through each bulkhead provided in each said small compartment, and a chemical reactive operation itself or part of the operation is performed by uniting it with the other droplet out of said plural kinds arranged in the other small compartments. (*See figure 1, 6-7, column 1 lines 20-30, column 3 line 65 – column 4 line 10, column 12 lines 50-65, column 13 lines 1-15 & 40-50, column 16 lines 35-45*).
30. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein is a protrusion within the channel and effectively sorts fluid as the bulkhead described in the specification where it separates the fluid into another compartment (*outlet 6*). Furthermore Ward teaches it would have been obvious to have bulkheads valleys, pits, or protrusions (*See Ward Figure 7 & [0289]-[0290]*) to define chambers for separation for the benefit of

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separating molecules based on molecular size, shape, and/or charge ([0134]).

31. Therefore it would have been obvious to modify the channel of Blankenstein with pits or bulkheads of Ward for the benefit of separating molecules based on molecular size, shape, and/or charge.

32. **Regarding claim 24, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein

33. when the optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed and which is arranged in the optional small compartment is conveyed to said other small compartment by said conveyance step by passing through each bulkhead provided in each said small compartment (*column 13 lines 1-10*),

34. the optional droplet out of said plural kinds to which said magnetic ultrafine particles are mixed is separated (*separation occurs after magnet 8 toward sort outlet 6, figure 1*) to the droplet that includes said magnetic ultrafine particles (*column 13 lines 5-9*) and the droplet that does not include said magnetic ultrafine particles (*column 13 lines 9-12*), by using physical and chemical characteristics such as wettability and surface tension of said droplet. (*column 13 lines 13-20*).

35. **Regarding claim 25, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein

36. by controlling the magnetic field (*field by magnet 8*) which is externally applied to the droplet to which said magnetic ultrafine particles are mixed, said magnetic ultrafine particles are dispersed and cohered in the inside of the droplet, and also the operation of a specimen that adhered to surfaces of said magnetic ultrafine particles is performed. (*Column 3 line 65 – column 4 line 10 & column 5 line 60-65, column 6 line 20-35, & column 9 lines 10-40*).

37. **Regarding claim 27, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein

38. in the condition where a specimen for performing chemical reactive operation adhered (*magnetically stained particles, column 3 line 67 column 4 line 9*) to surfaces of said magnetic ultrafine particles, said magnetic ultrafine particles are used as a carrier to perform the chemical reactive operation to said specimen. (*column 13 lines 1-15*).

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39. **Regarding claim 28, Blankenstein teaches** the chemical analytic apparatus according to claim 23, wherein
40. by combining a plurality of said small compartments (*the chamber of outlet 6 is where the magnetically stained particles are transferred, figure 1*) which are separated by plural bulkheads and which form the processing conditions by said processing steps, a series of chemical reactive operation by at least reaction, separation and dilution to the specimen that adhered to surfaces of said magnetic ultrafine particles is performed. (*See figure 1 & column 1 lines 20-30*).
41. Blankenstein does not explicitly teach compartments that are partially walled with bulkheads. However the fork in figure 1 of Blankenstein acts as a bulkhead described in the specification where it separates the fluid into another compartment (*outlet 6*). It would have been obvious to have protrusions or bulkheads to define chambers for separation.
42. **Claims 20 & 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blankenstein US Patent 6,432,630 (hereinafter "Blankenstein") in view of Ward et al. US Pre-Grant Publication 2004/0018611 (hereinafter "Ward").**
43. **Regarding claims 20 & 26, Blankenstein teaches** the chemical analytic apparatus above, wherein but does not teach the physical and chemical reaction control by at least light, heat or pH is used.
44. In the analogous art of magnetic separation in microfluidics Ward teaches reactions with light (*Ward [0049]*), heat (*raising temperature of the reaction in Ward [0143]*), and pH (*pH changes in Ward [0143]*) for the benefit of nucleic acid amplification (*[0143]*) in order to conjugate to a magnetic particle (*[0142]*).
45. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the reactions of Ward with the apparatus of Blankenstein for the benefit of nucleic acid amplification in order to conjugate to a magnetic particle (*[0142]*).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Pregler whose telephone number is (571)270-5051. The examiner can normally be reached on Monday through Friday 8am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Pregler/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797